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DEPARTMENT OF HEALTH & HUMAN SERVICES — PUBLIC HEALTH SERVICE

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Food and Drug Administration
Denver District Office
Building 20 - Denver Federal Center
P. O. Box 25087
Denver, Colorado 80225
TELEPHONE: 303-236-3000

December 11, 1996

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Robert D. Benzley
Owner/President
B&D Medical
4128 South Mobile Circle, Unit A
Aurora, Colorado 80013

PURGED

Ref. # - DEN-97-06

Dear Mr. Benzley:

During an inspection of your firm, B&D Medical, 4128 South Mobile Circle, Unit A, Aurora, Colorado on October 28, 30 & 31, 1996, Investigator Thomas B. Dowell determined that your firm repacks liquid and compressed medical oxygen. Medical gases are drug products as defined by Section 201(g) of the Federal Food, Drug, and Cosmetic Act (the Act). The above stated inspection revealed that your products are adulterated within the meaning of Section 501(a)(2)(B) of the Act in that the controls used for the manufacture, processing, packing, or holding of this product are not in conformance with current Good Manufacturing Practice Regulations under Title 21, Code of Federal Regulations (21 CFR), parts 210 and 211. Deviations noted during the inspection include, but are not limited to the following:

1. Failure to assay each batch of drug product for identity and strength prior to release as required by 21 CFR 211.165(a). For example, your firm performs no testing on bulk liquid oxygen received and distributed, nor do you witness such testing as performed by the supplier of the bulk liquid oxygen.

   Additionally, the only record obtained by your company regarding the purity of the bulk liquid oxygen is the invoice from the supplier. These invoices are inadequate in that seventeen of thirty reviewed do not have purity results or lot numbers recorded, or the test results are for a lot other than the bulk shipment received.

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2. Failure to retest drug product containers for identity after exposure to conditions that might adversely affect the drug product container, as required by 21 CFR 211.87. For example, no testing is performed on cryogenic units after their return from repair or maintenance.

3. Failure to establish a system by which distribution of each lot of drug product can be readily determined to facilitate its recall if necessary, as required by 21 CFR 211.150(b). For example, there is no use of a lot number or record of previous lot numbers to identify the liquid oxygen contained in the dewar, which is used to fill home units.

4. Failure to establish written specifications and test procedures designed to assure that the drug products conform to appropriate standards of identity, strength, quality, and purity, as required by 21 CFR 211.160(b).

5. Failure to establish written procedures for production and process control designed to assure that drug products have the identity, strength, quality and purity they purport or are represented to possess, as required by 21 CFR 211.100(a). For example, there are no written procedures for the filling of your liquid oxygen container, and subsequent transfer of drug product to home care patients.

6. Failure to establish written procedures for the handling of complaints, as required by 21 CFR 211.198.

7. Failure to maintain distribution records containing the name and strength of the product, the name and address of the consignee, and the date and quantity of drug product shipped, as required by 21 CFR 211.196.

For your information, you may use a Certificate of Analysis from your supplier to reduce the amount of testing your firm needs to perform. The Certificate of Analysis should contain the following information, at a minimum:

a. supplier's name;
b. the name of the product;
c. an air liquefaction statement;
d. lot number or unique identification number
e. actual analytical results obtained for identity and strength;
f. test method used for analysis; and
g. supplier's signature and date.

The above identification of violations is not intended to be an all inclusive list of deficiencies at your facility. As Owner and President, it is your responsibility to assure adherence with all requirements of the Good Manufacturing Practice Regulations.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action, including seizure or injunction, without further notice. Federal agencies are advised of the issuance of all warning letters for drug products so that they may take this information into account when considering the award of contracts.

Please advise this office, in writing, within fifteen (15) working days after receipt of this letter, of the specific actions you have taken to correct the violations. Your response should include: (1) each step that has or will be taken to completely correct the current violations and prevent the recurrence of similar violations; (2) the time when correction will be completed; (3) any reason why the corrective action is not completed within the response time; and (4) any documentation necessary to indicate correction has been achieved. Your response should be directed to Mr. David K. Glasgow, Acting Compliance Officer, at the above address.

Sincerely,

Gary C. Dean
District Director

bcc:

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ecc:

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